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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,829	02/21/2006	Ganugapati Vijaya Bhaskar	DAIRY88.011APC	2247

20995 7590 09/02/2009
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EXAMINER

BADR, HAMID R

ART UNIT	PAPER NUMBER
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1794

NOTIFICATION DATE	DELIVERY MODE
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09/02/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/540,829	Applicant(s) BHASKAR ET AL.	
	Examiner HAMID R. BADR	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Applicants' amendment filed on 4/16/2009 is acknowledged.

Claims 1-19 and 21-26 are being considered on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1-10 are indefinite for reciting in claim 1 "substantially" nugget free. It is unclear what is meant by "substantially". "substantially" is not defined by the claims nor is it explained in the specification. It is not clear what the applicants regard as the invention.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-11, 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Delespaul et al. (FR 2 452 879; Examiner's Translation; hereinafter R1).

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3. R1 discloses a process for making cheese. It specifically discloses a process for preparing milk products with improved texture. In classical cheese making, a coagulation stage is used where the milk is coagulated using an acid or pressure or notably microbial enzymes. (page 1, first two paragraphs).

4. R1 discloses that a more recent technique is the cheese making process by ultrafiltration consisting of concentrating milk proteins using membranes. (page 1, lines 9-12).

5. R1 discloses that the proteinaceous concentrate is coagulated by adding enzymes (rennet) and can be acidified by chemical acidification or bacteriological acidification (bacterial lactic fermentation) and by pressure to obtain cheese. The obtained cheese can undergo classical operations of acidification and aging. (page 1, line 26- page 2 line 1).

6. R1 discloses that the process of ultrafiltration has the advantage of improving the efficiency because the milk proteins which are ordinarily lost in the whey are incorporated in the curd. (page 2, lines 2-5).

7. R1 teaches of acidifying the milk before the ultrafiltration to solubilize part of the calcium which will be eliminated during the filtration process. (page 2, lines 23-26).

8. R1 teaches of heating the milk before the ultrafiltration process or heating the retentate of the ultrafiltration process to temperatures which can reach sterilization. This thermal treatment is effectuated at 75-150C and allows obtaining cheeses having fine and homogenous texture. R1 further explains that one can attribute the favorable effect of the heat treatment to partial denaturation of proteins or modification of the

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physical state of calcium present. (page 2, line 37- page 3, line7). The heat treatment should not be extensive, because due to extensive heat treatment, the viscosity of the product will be modified . (page 3, lines 9-11).

9. R1 discloses that the prepared material can be in the form of liquid or powder, or can be reconstituted and have fat, standardized by skim milk, or mixed with materials of animal or pant origin. The material can include 0-75% dry matter and preferably 40-50% (page 3, lines 31-36).

10. R1 teaches the decalcification of milk by ion exchange using cationic resins. Such resins can be charged for example by sodium, potassium, ammonium or hydrogen ion or by divalent ions such as magnesium, zinc, copper or trivalent ions depending on the salt concentration, pH and the desired composition of the material. (page 4, lines 4-12).

11. R1 discloses that the decalcification can be 0-80% and preferably 20-40% (page 4, line20-21). The decalcification extent will depend on the type of cheese desired (page 5, lines 22-26).

12. R1 discloses that the decalcification is optionally associated with a heat treatment between 75-150C and preferably 90-110C. R1 restates that the decalcification together with heat treatment will allow obtaining a fine and homogenous texture of cheese. (page 5, lines 26-31).

13. R1 discloses that when the decalcification process causes a total decalcification of milk or retentate, some soluble calcium can be added to allow the action of pressure and the coagulation which follows. (page 5, lines 32-36).

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14. R1 gives examples of making cheese using calcium depleted milk and rennet.

Decalcification is carried out to 30% in Example 1 and to 100% in Example 2. In Example 3, heat treatment is carried out by injection of vapor at 120C. (pages 6-7). The cheese is subjected to further processing (examples).

15. While R1 does not explicitly disclose a pH range at which whey proteins are heat denatured, the pH range as presently claimed is inherent to milk. R1 also discloses the heating process and attributes the favorable effect of the thermal process treatment to a partial denaturation of proteins. (page 3). Therefore the newly introduced limitation of heating the milk at pH 6.0-7.0 is anticipated by R1.

16. Given that R1 discloses processes for the preparation of milk protein concentrate (MPC) or isolate (MPI) through calcium depletion, the preparation will have higher solubility than MPC and MPI without calcium depletion. The cold solubility will be inherent in the product and the solubility in cold aqueous media will be in the range as presently claimed.

17. Given that the MPC and MPI products as disclosed by R1 contain whey proteins, it is clear that the whey protein content will be in the range as presently claimed.

18. Given that the ultrafiltered material as disclosed by R1 has 22% dry matter and this dry matter is 70% protein (Example 1, 2, 3), upon drying; such a product will have dry matter, as milk protein, in the range as presently claimed.

19. Given that R1 discloses method as presently claimed, it is clear that the cheese would inherently be substantially nugget free as presently claimed.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 7, 12-19, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Delespaul et al. (FR 2 452 879; Examiner's Translation; hereinafter R1) in view of Bhaskar et al. (WO 01/41578; hereinafter R2).

22. The disclosure by R1 is hereby incorporated by reference as outlined in paragraphs 3-14 above.

23. While R1 discloses the temperature range at which the heat treatment can be carried out, and it specifically points out to the point that extensive denaturation will affect the viscosity of the product, it does not mention duration of time during heat treatment. However, knowing the temperature in the range as taught by R1, those of skill in the art can optimize the time required for heat treatment as presently claimed.

24. R1 is silent using chelating agents for decalcification, or indirect means of heat treatment of the material, or a specific pH at which heat treatment is performed.

25. R2 discloses the preparation of milk protein concentrate (MPC) or isolate (MPI) having at least 70% dry matter as milk protein and using them in cheese making. The calcium depleted MPC and MPI will allow the manufacture of nugget free cheese.
(Abstract).

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26. R2 teaches that when the calcium removal is by way of addition of chelating agents, citric acid, EDTA. The chelating agents are used in conjunction with dialysis and or ultrafiltration and diafiltration. (page 4, lines 10-14).

27. R2 teaches that the liquid product can be dried using falling film evaporators and spray drying. (page 4, lines 31-33).

28. R2 teaches that pH of MPC or MPI when applied to cation exchanger is in the range of 5.6-7. If after passage through the ion exchange column the pH increases above 7.0, it will be adjusted to 6.5-7.0 to make it more palatable (page 5, lines 14-17).

29. R2 disclose a process for preparing a dried MPC or MPI (page 6, steps a-e).

30. It would be also obvious to perform the heat treatment using indirect heat heating as presently claimed. An example of indirect heating is a plate heat exchanger which is well known in the art.

31. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to follow the teachings of R1 and R2 to prepare high yield MPC and MPI of the presently claimed invention which results in more consistent and efficient cheese making (page 1, lines 21-23, R2). Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in preparing calcium depleted milk concentrates.

Response to Arguments

Applicants arguments have been thoroughly reviewed. These arguments are not persuasive for the following reasons.

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1. Applicants argue that the Examiner objected to the use of “substantially nugget-free” in claim1 while “substantially nugget free “ is understood by an artisan.

a. Firstly the claims containing the phrase “substantially nugget-free” have been rejected under 112(2) not objected to as the applicants state. Secondly, the rejection is maintained because “substantially” is not defined in the claims or in the specification.

2. Applicants argue that Delespaul does not anticipate claims 1-11 and 25-26 because the claimed processes enhance the cold solubility of the MPC or MPI by calcium depletion and that the denatured protein allows greater retention of protein with the curd in the cheese making process.

a. Please refer to pages 6-7 and Examples 1-3 of the official translation of the Delespaul (provided to Applicants) to find about both the decalcification and heat treatment of milk proteins. The attributes of cold solubility (dispersibility) and higher yield due to greater retention of proteins with the curd in the cheese-making process are inherent in the treated milk product of R1.

3. Applicants argue that the heat treatment of milk at pH 6.0-7.0 is not disclosed by Delespaul.

a. Milk has a normal pH range of about 6.0-7.0. Therefore, the heat treatment of the milk product as disclosed by Delespaul is inherently carried out at this pH range. On the other hand. Please see Examples 1-3 for heat treatment of milk at an inherent pH of 6.0-7.0.

4. Applicants argue that Delespaul does not teach forming dried calcium-depleted heat treated MPC or its use in Cheese making.

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a. Forming a dried MPC is disclosed in claim 18 of the instant application. Claim 18 is not rejected under Delespaul only. R1 in view of R2 will make the formation of dried MPC an obvious process.

5. Applicants argue that the cheese produced by Delespaul would not be substantially nugget free because Delespaul does not disclose processing dried MPC.

a. It is agreed that Delespaul does not disclose a dried MPC, however, since Delespaul employs calcium depleted and heat treated concentrated milk, the cheese produced using the treated milk product, of Delespaul, will be substantially nugget free. In other words the end result of using the Delespaul product or reconstituting the dried MPC as presently claimed would be the nugget free cheese. The whole emphasis of Delespaul is preparation of a cheese having a fine and homogenous texture. (please see paragraph 3 on page 7 of the official translation provided to you).

Further, it is noted that while Delespaul does not disclose a dried milk protein concentrate (MPC), in light of the open language of the present claims, i.e.

"comprising", the claims are clearly open to the inclusion of additional components including the calcium depleted, heat treated milk product disclosed by Delespaul.

6. Applicants argue that there is no teaching or suggestion of heat treatment of whey proteins by Delespaul and that Bhaskar focuses on preparation of calcium depleted MPC.

a. Please see page 7, third paragraph (official translation of Delespaul) for the heat treatment. The whey proteins contained in the milk being heat treated will be denatured.

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The denaturation of whey proteins will be inherent to the heating process. Please also see page 4 (translation) first paragraph for the effect of heat.

7. Applicants argue that Bhaskar does not make up for the heat treatment deficiency because Bhaskar does not teach a heat treatment step.

a. Bhaskar does not have to teach heat treatment because Delespaul teaches that limitation. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

8. Applicants argue that even if the combination of Delespaul and Bhaskar is proper, one skilled in the art would have no reasonable expectation of success of modifying Bhaskar with a heat treatment step.

a. It should be realized that applicants are claiming the decalcification process through the use of chelating agents. Bhaskar discloses that portion of the claim.

9. Applicants argue that Delespaul teaches away from the combination because Delespaul cautions against excessive denaturing of the proteins.

a. Excessive denaturation of proteins is not a requirement in the presently claimed invention, therefore, Delespaul does not teach away from the invention.

Conclusion

No claims are allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794